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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,668	12/18/2001	Stephen Griffin	1001.1535101	6574
28075	7590	06/06/2006	EXAMINER	
CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			FOREMAN, JONATHAN M	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/025,668	Applicant(s) GRIFFIN ET AL.	
	Examiner Jonathan ML Foreman	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 20-44 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 20-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 5, 6, 20, 24, 25 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,957,966 to Schroepel et al.

In regards to claims 1, 5, 6, 20, 24, 25 and 39, Schroepel et al. discloses an elongate core wire (42) comprising a metal and having an outer surface and a distal end; and a polymer jacket comprising a shape memory polymer attached to and encasing a portion of the core wire such that a substantial portion of the jacket is juxtaposed with the outer surface of the core wire, the polymer jacket being more stiff than the portion of the core wire which it encases (Col. 6, line 36 – Col. 7, line 3); wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first and second shape (Col. 5, lines 47 – 52). The shape memory polymer comprises polyurethane or polynorborene (Col. 7, lines 46 – 50).

3. Claims 1, 36, 37, 39 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication No. 2002/0183654 to Zhou.

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4. In regards to claims 1, 36, 37, 39 and 40, Zhou discloses an elongate core wire (106) comprising a metal and having an outer surface and a distal end; and a polymer jacket (128) comprising a shape memory polymer attached to and encasing a portion of the core wire such that a substantial portion of the jacket is juxtaposed with the outer surface of the core wire a portion of the core wire [0021], the polymer jacket being more stiff than the portion of the core wire which it encases [0028][0029]; wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first and second shape. The portion of the core wire surrounded by the polymer jacket includes a tapered portion (130).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 7 – 16 and 26 – 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,957,966 to Schroepel et al. in view of U.S. Patent No. 6,485,458 to Takahashi.

In reference to claims 7 – 16 and 26 – 35, Schroepel et al. discloses a shape memory polymer surrounding a portion of the core wire being polynorborene, polyurethane and similar materials (Col. 7, lines 46 – 50), but fails to disclose the polymer being polcaprolactone, polymethylmethacrylate, PLLA, PLLA OGA, PL/D LA, PMMA, polyethylene, polyisoprene, styrene-butadiene or photocrosslinkable polymer. However, Takahashi discloses a shape memory

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polymer surrounding a core wire wherein the polymer consists of poluorbornen, styrene-butadiene, polyisoprene, polyester, polyolefin, acrylic and styrene-acrylic (Col. 5, lines 56 – 67). Takahashi teaches that other shape-memory materials can be used in addition to those disclosed. It would have been obvious to one having ordinary skill in the art at the time the invention was made use any shape memory polymer as taught by Takahashi in the device as disclosed by Schroepfel et al. in that Takahashi teaches that shape memory polymers are interchangeable. Additionally, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, replacing the shape memory polymer as disclosed by Schroepfel et al. with any other shape memory polymer is a design consideration within the skill of the art.

7. Claims 1 - 5, 20 – 24 and 36 – 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,452,726 to Burmeister et al. in view of US Patent No. 6,024,764 to Schroepfel.

In regards to claims 1 - 5, 20 – 24 and 36 – 44, Burmeister et al. discloses an elongate core wire comprising stainless steel or a nickel titanium alloy (Col. 2, lines 38 – 41) and having a tapered portion (24, 30); and a polymer jacket (42; Col. 3, line 65 – Col. 4, line 9) attached to and encasing a portion of the core wire such that a substantial portion of the jacket is juxtaposed with the outer surface of the core wire a portion of the core wire including the tapered portion. However, Burmeister et al. fails to disclose the polymer jacket being a shape memory polymer more stiff than the portion of the core wire which it surrounds; wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first and second shape. Schroepfel discloses a guiding element for

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positioning within a patients body (Col. 5, lines 12 – 15) including a polymer jacket being a shape memory polymer more stiff than the portion of the core wire which it surrounds (Col. 5, lines 41 – 57); wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first and second shape. Schroepfel discloses that any number of different types of tubular devices can include such a jacket (Col. 3, lines 53 – 57). It would have been obvious to one having ordinary skill in the art to modify the polymer jacket as disclosed by Burmeister et al. to include a shape memory polymer as taught by Schroepfel so the device can be shaped by a surgeon into a shape and subsequently reshaped if desired to allow for introduction into the patient's anatomy (Col. 5, lines 50 – 60).

Response to Arguments

8. Applicant's arguments filed 3/14/06 have been fully considered but they are not persuasive. Applicant asserts that Schroepfel et al. fails to disclose a polymer jacket attached to a portion of the core wire. However, the Examiner disagrees. Schroepfel et al. clearly discloses a polymer jacket (28 and 30) being attached to a core wire (42) in that the core wire (42) is attached to the tip electrode (22) which is attached to segment (26) which is attached to polymer jacket (28) (See Col. 4, lines 42 – 51 and Col. 5, lines 8 – 10). Applicant asserts that Zhou fails to disclose a polymer jacket which encases a portion of the core wire. Applicant argues that the polymeric jacket (128) must be spaced from the core wire (106, 138) and therefore does not encase the core wire. However, the Examiner disagrees. Firstly, the claim does not require the polymer jacket to be in contact with the core wire, but to merely encase (i.e. enclose within) the core. Secondly, Zhou discloses at least a portion of the polymer jacket contacting and surrounding a portion of the core [0017]. In regards to the rejection under 35 U.S.C. §103(a) over Burmeister et al. in view of Shroepfel, Applicant asserts that

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Schroeppel fails to teach a polymer jacket being more stiff than the portion of the core wire which it surrounds. However the Examiner disagrees. The polymer jacket is used to shape the core wire which it surrounds, therefore, the polymer jacket is more stiff than the portion of the core wire which it surrounds. Shroeppel discloses the polymer jacket for use in many devices including endocardial leads (Col. 5, lines 5 – 10), of which at least a portion must be a metallic material.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. JP 03-03033809A to Nakamura discloses a core wire surrounded by a shape memory polymer, the polymer being more stiff than the portion of core wire which it surrounds (See Abstract).

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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